

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

**IN RE: ETHICON, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY
LITIGATION**

**Master File No. 2:12-MD-02327
MDL 2327**

**JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE**

**MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION
TESTIMONY OF ROBERT BRIAN RAYBON, M.D.**

Brian Raybon, M.D. seeks to offer various opinions regarding the ability of Prolift and Prolift + M products to cause the injuries alleged by the several plaintiffs in this litigation. This Court's rulings and Dr. Raybon's testimony show that these opinions are inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), including:

- **Opinions regarding various complications associated with Prolift and Prolift + M.** This Court has repeatedly excluded Dr. Raybon's general-causation opinions because Dr. Raybon's experience does not qualify him to opine on the cause of various complications experienced by pelvic mesh patients and also, even if he were qualified, his general-causation opinions are unreliable.
- **Opinions regarding competency and training of other physicians.** These opinions are irrelevant, speculative, and misleading.
- **Opinions about clinical study results, and opinions that Prolift devices have unacceptable complication rates and unacceptable risk/benefit profiles.** Dr. Raybon admits he is not an expert on clinical studies, and his risk/benefit opinions and opinions as to what is an "unacceptable" complication rate are pure *ipse dixit* personal opinions and are irrelevant.
- **Opinions that the Prolift IFU and warnings were inadequate.** Dr. Raybon is not qualified to offer these opinions and they are nothing more than unreliable personal opinions.
- **Opinions regarding safer alternative designs.** Dr. Raybon admits these opinions lack factual support.

- **Opinions relating to infection, fistulae, and abscesses.** The Court has repeatedly excluded this opinion testimony in other cases.
- **Opinions regarding FDA regulatory requirements or issues.** These opinions lack factual support, are unreliable, and have been excluded by this Court.
- **Opinions relating to corporate knowledge, state of mind, motives, or intentions, and narrative review of corporate documents.** This Court has repeatedly excluded this type of opinion testimony in other cases.

As more fully explained below, Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) ask that these opinions be excluded.

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Raybon is Not Qualified to Render General-Causation Opinions That Polypropylene Mesh Products Cause Various Complications and His Opinions Are Unreliable.

Throughout his Rule 26 Reports regarding Prolift and Prolift + M, Dr. Raybon offers various opinions regarding the clinical effects of these products. Each report, for example, contains a section which, by its title, is apparently intended to indicate why the products were defectively designed. Ex. C, Rule 26 Report (Prolift) at 3-11; Ex. D, Rule 26 Report (Prolift + M) at 3-11. Regarding the mesh used in Prolift and the transvaginal implant technique, Dr. Raybon opines that “[t]he mechanical stresses imposed by the side to side attachment via the arms in combination with the shrinkage by the mesh cause patients pain.” Ex. C at 6; Ex. D at 8. Dr. Raybon also states his “belief” that Prolift mesh degrades over time and “that this degradation is an ongoing process that can cause clinical issues years down the road remote from the initial implantation.” Ex. C at 7; Ex. D at 8-9.

Beyond the general-causation opinions Dr. Raybon discusses in his design-defect sections, Dr. Raybon also has a separate specific section in each Rule 26 Report titled “General Causation,” which contains a laundry list of complications he says he has observed in patients implanted with these products. Both lists identify:

- Chronic or permanent pelvic pain;
- Chronic or permanent inflammation of tissue surrounding the mesh;
- Excessive scar plate formation, scar banding, and contracture of mesh arms, resulting in asymmetrical pulling on the central portion, causing pain;
- Erosion of mesh into the bladder and/or rectum and exposure of mesh in the vagina;
- Pudendal neuralgia;
- Pelvic floor muscle spasm;
- Dyspareunia;
- Stress urinary incontinence and urge incontinence;
- Urinary retention;
- Constipation or fecal incontinence;
- Deformed, wrinkled, folded, curled, roped, and fragmented mesh upon removal;
- Encapsulation of mesh (mesh covered in thick scar);
- Vaginal shortening, tightening, stenosis and/or other deformation of the pelvic anatomy;
- Infection, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses;
- Recurrence of prolapse (failure of treatment); and,
- Nerve damage or nerve entrapment as a result of mesh scarification and encapsulation (Prolift) or as a result of mesh scarification and fibrotic bridging (Prolift + M).

In addition, his list of complications allegedly caused by Prolift + M includes:

- Nerve injury/damage and direct trauma to organs and tissues caused by blind passage of trocars; and,
- Fistulae.

Ex. C at 22-23; Ex. D at 16-17. According to Dr. Raybon, each of these complications is “directly attributable” to the defective design of the Prolift products. Ex. C at 23; Ex. D at 17.

This Court has twice previously excluded these opinions as proposed by Dr. Raybon because he lacks the qualifications to render them and also because they are unreliable,

unscientific observations based on nothing more than Dr. Raybon's personal observations and opinion. *See Eghnayem v. Boston Scientific Corp*, 57 F. Supp. 3d 658, 701 (S.D.W. Va. 2014); *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *16 (S.D.W. Va. Feb. 7, 2015). As this Court stated, Dr. Raybon's general-causation opinion testimony "goes beyond his experience with pelvic mesh" because Dr. Raybon "is not a specialist in the etiology of pelvic and vaginal pain." *Eghnayem*, 57 F. Supp. 3d at 701. As a result, Dr. Raybon, "lacks the qualifications to infer from [his personal] observations as to the etiology of complications associated with a pelvic mesh device." *Wise*, 2015 WL 521202, at *16. Dr. Raybon has not disclosed any additional expertise that would provide a basis for reaching a different conclusion in this case. "Furthermore, Dr. Raybon's general causation opinions do not satisfy the reliability requirements of *Daubert*" because they are "based solely on his experience as a physician." *Eghnayem*, 57 F. Supp. 3d at 701.

To the extent Plaintiffs attempt to cure the reliability element of this Court's *Eghnayem* and *Wise* exclusions of Dr. Raybon, by claiming Dr. Raybon's general causation opinions rest on medical literature he refers to generally in his Prolift reports, their argument fails. First, Dr. Raybon indicates that any medical literature he relies on for his general-causation opinions "discusses these complications with *other* transvaginal pelvic organ prolapse repair implants." Ex. D at 17 (emphasis added). Moreover, Dr. Raybon's deposition testimony reveals that his opinions here are still subject to deficiencies of experience and reliability.

Dr. Raybon's baseline opinion is that Prolift and Prolift + M cause chronic and permanent pelvic pain. He attributes that pain to the arms on the devices, "as well as the chronic and ongoing inflammatory/foreign body response induced by degrading polypropylene," and "poor surgeon training." Ex. E, Raybon 4/18/16 Dep. Tr. 234:17-24. Dr. Raybon explains,

however, that his reference to the arms of Prolift mesh is really a statement that the arms are “digging up some of the nerves and so forth.” *Id.* at 242:3-4. In other words, his opinion about the arms is that the placement causes nerve damage. Dr. Raybon likewise explains that “chronic inflammation” is also really a reference to nerve damage. *Id.* at 238:13-16 (“Once the nerves—this has been well-described—are chronically irritated, their threshold for wanting to fire is actually lowered dramatically.”).

In essence, Dr. Raybon’s general-causation opinions rest on either nerve damage (through chronic inflammation or placement of the arms) or surgeon training or technique.¹ *Id.* at 235:7-12 (“chronic or permanent inflammation of tissues surrounding mesh” is caused by mesh degradation); *see also id.* at 236:7-15 (“inflammation and chronic inflammation” causes erosion of mesh into bladder and rectum and exposure of mesh into vagina.”); *id.* at 236:16-237:11 (pudendal neuralgia caused by ensnaring or laceration of pudendal nerve and chronic inflammation); *id.* at 238:7-16 (pelvic floor muscle spasms caused by chronic “irritation and inflammation of the nerves”); *id.* at 239:12-240:2 (nerve damage and dyspareunia can be the result of nerve damage and “the nerve damage can be many ways”); *id.* at 241:10-242:10 (urinary retention caused by “digging up some of the nerves” and stress urinary incontinence caused by “chronic irritation and inflammation going on and lowering the threshold for the nerves to fire.”).

This Court’s original exclusion of Dr. Raybon’s general-causation testimony expressly rejected Dr. Raybon’s attempt to opine about whether a mesh product can cause nerve damage. *Eghnayem*, 57 F. Supp. 3d at 700-01 (“Dr. Raybon’s opinion testimony, on the other hand, goes

¹ That Dr. Raybon’s general-causation opinions also rest on his characterization of surgeon competency provides another basis for excluding his opinions as irrelevant. *See Section II infra.*

beyond his experience with pelvic mesh. He is not a specialist in the etiology of pelvic and vaginal pain, and his awareness of any relationship between nerve trauma and mesh products is limited to his experience in diagnosing fifteen to twenty post-implantation patients.”).

Dr. Raybon’s general-causation opinions here are the same opinions—Prolift causes chronic inflammation, which ultimately causes nerve damage. He is no more qualified and his opinions no more scientifically robust or reliable here than when the Court twice previously excluded these same general-causation opinions. The outcome should be no different here.

II. Dr. Raybon’s Opinions Regarding the Competency of Other Physicians, Including General-Causation Opinions Resting on This Basis, Should be Excluded as Irrelevant, Speculative, and Misleading.

This Court has already ruled that opinions regarding the competency of other physicians are irrelevant and will not assist the jury. *Edwards*, 2014 WL 3361923, at *17. In doing so, the Court precluded the plaintiff’s expert from testifying that: (1) it is difficult to learn the surgical technique to implant TVT-O, (2) it is easy to misguide the trocars, (3) Ethicon trivialized the learning curve and potential complications, and (4) surgeons with inadequate skill and experience performed these surgeries. *Id.* Likewise, this Court has also previously excluded Dr. Raybon’s proposed opinions regarding physician training because those opinions depend on the competence of other physicians and, as a result, are irrelevant. *Wise*, 2015 WL 521202, at *13.

Despite these prior rulings in *Wise* and *Edwards*, Dr. Raybon intends to offer extensive testimony about the training and overall competency of surgeons to implant Prolift devices. Ex. C at 23. This includes, but is not limited to, testimony that “Ethicon’s physician training program for the Prolift kits was inadequate, and resulted in the ‘certification’ of numerous physicians who were undertrained and who lacked the experience, skills and expertise necessary to properly perform the implantation of these products” and that, as a result, physicians who “never went to training, had not attended a fellowship, nor had significant clinical experience to draw on”

performed Prolift implants even though they “likely did not understand the proper technique for implanting Prolift.” *Id.* at 23-24. Dr. Raybon will testify that Ethicon allowed “a broad group of physicians to train, which resulted in non-expert surgeons performing a procedure that is unsafe in the hands of most surgeons.” *Id.* at 27. Dr. Raybon also intends to opine that there is a purportedly “dangerous” or “unreasonably dangerous” risk of tissue damage, vascular damage, nerve damage, and internal trauma associated with “the blind passage of the metal trocars during implantation.” Ex. C at 9; Ex. D at 9. Dr. Raybon intends to offer his opinion that “too often this [experienced surgeon with an in-depth knowledge of female pelvic anatomy] was not the surgeon Ethicon chose to work with.” Ex. C at 9; Ex. D at 9. Dr. Raybon also identifies “poor surgeon training” and “surgical technique” as supposed defects in the Prolift devices which support his general-causation opinions. *See* Ex. E, Raybon 4/18/16 Dep. Tr. 234:23-24 (“I think that the other thing [which causes chronic or permanent pelvic pain] is poor surgeon training.”); *see also id.* at 236:7-12 (Q. “What defect in the Prolift or Prolift + M devices causes erosion of mesh into the bladder and rectum and exposure of mesh into the vagina?” A. “Once again, obviously, you can’t say something like that without commenting on surgical training and surgical technique.”); *id.* at 236:19-21, 237:7-9 (“[I]t can be the actual technique [of passing the trocars blindly] itself, whether it’s from poor design by a manufacturer or the execution of that by the surgeon [which causes pudendal neuralgia].”); *id.* at 241:16-19 (“One [thing which causes urinary retention] is going to be perhaps related to the dissection or improper dissection required[.]”); *id.* at 242:5-7 (“As far as the stress urinary incontinence goes, I think some of that has to do with, once again, with the training there.”).

These general-causation opinions rest on the claim that alleged injuries were sustained due to poor surgeon training or technique, and are nothing more than opinions about the

competency of other physicians. As they were in *Wise* and *Edwards*, these irrelevant opinions say “little about the design of [Prolift] or the adequacy of its warnings” and should be excluded here. *Wise*, 2015 WL 521202, at *13.

Nor do these opinions survive Rule 403 balancing because they are misleading and confusing to the jury. Dr. Raybon’s testimony about general surgical difficulty and other physicians’ theoretical experiences and training could mislead the jury into inferring that the Plaintiffs’ respective surgeons actually experienced difficulty implanting the Prolift devices or were not properly qualified or trained. The only proper source of that evidence is each respective surgeon’s testimony and medical records. For these reasons as well, Dr. Raybon’s competency opinions should be excluded.

III. Dr. Raybon Is Not An Expert In Clinical Studies, and His Opinions That the Results of Clinical Studies Indicate Prolift Devices Have An “Unacceptable” Complication Rate or Unacceptable Risk/Benefit Profile Are Irrelevant and Pure *Ipse Dixit*.

Dr. Raybon admits he is not an expert in “the design of clinical trials or testing of medical devices.” Ex. E, Raybon 4/18/16 Dep. Tr. 224:6-9. Indeed, this Court has previously concluded that Dr. Raybon’s “experience as a pelvic surgeon does not qualify him to speak on this matter.” *Wise*, 2015 WL 521202, at *16-17.

Notwithstanding this acknowledged lack of competence and this Court’s prior exclusion of his opinions on these subjects, Dr. Raybon purports to analyze multiple clinical trials involving either Prolift devices or the Gynemesh material used in Prolift and offers opinions about the results. For example, Dr. Raybon cherry picks a certain part of the results of a Prolift clinical trial, asserts that those results should have been conveyed to physicians, and opines that Ethicon “failed to adequately provide any warning or information to physicians about the results

of this study.” Ex. C. at 19-20. Dr. Raybon then purports to analyze a *different* Prolift clinical study conducted and opines that “success” was “arbitrarily defined.” *Id.* at 20.

Dr. Raybon carries this criticism of the second study forward as the basis for comparing results of the two studies and concluding that “[t]hese results further demonstrated that the risks of this product outweighed any potential benefit.” *Id.* And from that comparison, Dr. Raybon opines, again, that “surgeons should have been warned about the overall complication rates and that the device was a failure for two of the three groups of U.S. patients under Ethicon’s own criteria.” *Id.* He claims that his analyses of the clinical studies show “unacceptable rates” of complications, which he says were caused by the devices and also demonstrated “an unacceptable risk/benefit profile for the Prolift.” *Id.* at 4, 21.

As this Court has recognized, Dr. Raybon “has no demonstrated training in, knowledge of, or experience with the design of clinical trials or the process of testing medical devices[.]” *Wise*, 2015 WL 521202, at *16-17. Although he attempted to conduct a critical analysis of these studies, he did no such thing. Instead, he pulled out segments of results from different studies looking at different things as the basis for his opinions about the risk/benefit profile and complication rates for Prolift devices. Dr. Raybon steps too far and exceeds his qualifications. All clinical-trial opinions and testimony should be excluded.

Dr. Raybon’s “unacceptable” complication-rate opinion is also unreliable. He identifies no methodology for determining what constitutes an “unacceptable” complication rate for Prolift. Ex. E, Raybon 4/18/16 Dep. Tr. 229:18-232:20. Dr. Raybon’s unacceptable complication-rate opinion is no more than *ipse dixit*, or a personal opinion, and should be excluded on that basis. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *31-32 (S.D.W. Va. Sept. 29, 2014) (finding subjective and

conclusory approach to opinion demonstrated mere speculation and personal belief warranting exclusion of the opinion as unreliable).

IV. Dr. Raybon is Not Qualified to Offer Opinions Regarding the Adequacy of the Content of Prolift's IFU and Warnings, and His Warnings Opinions Are Unreliable Personal Opinions.

Dr. Raybon has never drafted an IFU or a warning to accompany a medical device, and does not know the FDA's regulations or regulatory processes relating to warnings. Ex. E, Raybon 4/18/16 Dep. Tr. 223:9-224:2. Nevertheless, Dr. Raybon offers many opinions that the Prolift IFUs "failed to adequately warn" because they (1) contained "false" statements or (2) did not contain various separate warnings Dr. Raybon contends should have been included. Ex. C at 11-19; Ex. D at 11-15. Because he admits he has no experience, let alone expertise, with respect to warnings and IFUs, Dr. Raybon is unqualified to offer any testimony about Prolift's warnings or IFU, including opinions about the adequacy or inadequacy of the warnings and IFU, and opinions about whether the warnings/IFU satisfy FDA regulations.

This Court has permitted some experts for some plaintiffs to testify about warnings in a more restricted way that allows the expert to identify the risks the expert perceives are posed by the device and then state his or her opinion that the relevant IFU did not convey these risks. Under the circumstances present here, however, Dr. Raybon should not be permitted to give even that limited testimony.

First, Dr. Raybon's opinions are all framed so as to state that the IFU was actually *inadequate* in a general sense because it did not have the warnings Dr. Raybon proposes. His opinions, therefore, go "a step further than comparing the risks of the product to the content of the label." *Wise*, 2015 WL 521202, at *5 n.4. Moreover, Dr. Raybon does not tie his warnings opinions to FDA regulations or compliance. Imposing a restriction prohibiting Dr. Raybon from opining about compliance with FDA regulations is no limitation at all.

Perhaps more importantly, Dr. Raybon admits he literally has *no methodology* for evaluating warnings or an IFU that would allow Defendants to understand his warnings opinions and examine how reliable they are. Ex. E, Raybon 4/18/16 Dep. Tr. 192:20-193:9. Nor does Dr. Raybon even try to create or apply any sort of actual methodology to arrive at his warnings opinions. Instead, he assesses Prolift warnings and IFUs with what he cavalierly calls the “obscenity” standard—“I think I know a good IFU when I see it.” *Id.* Thus, by his own admission, Dr. Raybon’s warnings opinions are the truly perfect example of opinion testimony based not on a reliable methodology, but on pure personal opinion and *ipse dixit*.

Dr. Raybon asserts at least 18 different opinions related to alleged warning inadequacies in the Prolift IFU. The supposedly missing items include warnings about:

- Lack of FDA clearance or approval;
- Excessive inflammation and foreign body reaction;
- Inadequate pore size;
- Severe prolapse patients are better Prolift candidates;
- Shrinkage was 20-40%;
- Shrinkage and dyspareunia before 2009;
- Increased risk of complications in connection with hysterectomy;
- Clinical study results regarding painful mesh shrinkage;
- Complication results from a European clinical study;
- Potential need for additional surgery to address certain potential complications;
- Nerve damage before 2009;
- Prolift arms tearing tissue during implant procedure;
- Mesh arms would deform;
- Risk of nerve injury;
- New complications following implant;
- Removal requires invasive and difficult surgery;
- Restriction of implant candidates; and
- The importance of leaving no tension in mesh arms while implanting the device.

Ex. C at 11-19, 24-27; Ex. D at 11-15. This comprehensive list of alleged IFU and warning deficiencies permeates the rest of Dr. Raybon’s general opinions as well.

As the Fourth Circuit has recognized, “expert witnesses have the potential to be both powerful and quite misleading.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). The potential to be misleading is great here. Indeed, the jury will likely hear (1) Dr. Raybon only ever implanted 25 Prolift devices, and (2) none of those 25 were Prolift + M. Ex. E, Raybon 4/18/16 Dep. Tr. 56:4-11; 74:19-21. Yet allowing Dr. Raybon to say he implanted 25 devices and then identify almost 20 issues he says are complications he has observed with Prolift devices but that are not in the IFU for Prolift would be extremely misleading. The obvious reason for presenting that evidence to the jury would be to suggest the complication information should have been in the IFU, even if Dr. Raybon does not say so expressly. There is no other logical purpose for doing so.

Whether it is the full scope of his original proposed warnings opinions or a modified version, *Daubert* still demands a reliable methodology. Dr. Raybon admits there is no methodology supporting his warnings opinions and that they are strictly his personal opinions. Ex. E, Raybon 4/18/16 Dep. Tr. 192:20-193:9. This type of analysis by an expert does not satisfy *Daubert* in any circumstance and it is not sufficient to merely limit Dr. Raybon’s warnings testimony in the way this Court has done with previous experts.

Finally, even if Dr. Raybon is limited in his warnings opinions, the Court should exclude Dr. Raybon’s opinion that Ethicon’s alleged failure to warn physicians and patients about known risks associated with the Prolift and about the frequency, severity, and duration of the risks that were disclosed “rendered the Prolift not reasonably safe.” Ex. C at 14. This opinion “invades the province of the jury by stating a legal conclusion” and should be excluded. *Wise*, 2015 WL 521202, at *4 n.4. This Court has also excluded this type of opinion testimony for lack of reliability where the expert can point to no support—and Dr. Raybon provides none here—

showing that a manufacturer should include frequency, severity, and duration of risk information in its IFU. *See Frankum v. Boston Scientific Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at *21 (S.D.W. Va. May 1, 2015) (excluding warnings opinion that frequency-severity information should be included in the manufacturer’s IFU where there was no support that this information should be included). It should be excluded here as well.

V. Dr. Raybon’s Opinions Regarding Safer Alternative Designs Are Not Reliable Because They Are Not Supported by Sufficient Facts or Data.

Expert testimony is only admissible under Rule 702 if it is “based upon sufficient facts or data”—*i.e.*, if it “rests on a reliable foundation.” *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014) (citing Rule 702 and *Daubert*, 509 U.S. at 597). Dr. Raybon proposes to testify that Ethicon had “several alternatives to the design of the Prolift kits that would have been safer.” Ex. C at 22. These supposed safer designs include use of polyvinylidene fluoride, elimination of permanent mesh arms, elimination of blind trocar passes, and introduction of stress shielding. *Id.* Dr. Raybon’s deposition testimony shows he is speculating that these proposed design alternatives would, in fact, be safer.

Dr. Raybon concedes there are more clinical studies published regarding Prolift than any other transvaginal mesh device. Ex. E, Raybon 4/18/16 Dep. Tr. 157:12-17. He further concedes that there is no valid scientific evidence showing polyvinylidene fluoride was a safer alternative, but that there are only internal Ethicon documents that showed Ethicon was developing that substance and was encouraged by development results. *Id.* at 158:14-159:13. Dr. Raybon cannot identify any published peer-reviewed data—or any other data for that matter—showing another mesh material was safer and more effective for treating pelvic organ prolapse than polypropylene. *Id.* at 159:14-20.

Dr. Raybon admits his proposal to do away with the mesh arms or have mesh arms that go away after implant is nothing more than “an interesting concept.” *Id.* at 161:1-162:2. He also admits he has not done and is not aware of any testing or experiments to investigate the feasibility or safety of any of his theoretical proposed alternative design features. *Id.* at 162:17-163:8. In fact, he says he and several other people were at one time “looking at some designs” but admits he has “no knowledge if any of those [potential alternative designs] ever went anywhere.” *Id.* Regarding Prolift + M, Dr. Raybon suggests an absorbable component other than monocryl should be used, but admits he does not even have a proposed alternative substance that he would advocate as safer. *Id.* at 167:13-168:9.

Based on these admissions, Dr. Raybon should be precluded from offering opinions regarding safer alternative designs.

VI. Dr. Raybon’s Opinions Regarding Infection, Fistulae, and Abscesses Should Be Excluded in Cases In Which None of Those Conditions is Alleged.

The Court has excluded opinions regarding mesh-related infections as irrelevant where the Plaintiff has not alleged infection. *See In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied sub nom. In re Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014) (excluding infection-related testimony of Plaintiffs’ expert Dr. Klinge in case where Plaintiff did not allege infection). An expert witness may only testify if his or her “scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue.” *Id.* (citing Rule 702) (emphasis in original).

It is Dr. Raybon’s opinion that implanting the Prolift mesh through the vagina necessarily places the mesh and its pores in contact with “[l]arge amounts of bacteria.” Ex. C at 11. According to Dr. Raybon, the bacteria “can attach to the mesh, where the bacteria can

proliferate, and result in abscesses, fistulae, infection, and chronic or permanent inflammation.”

Id. The three cases to which Dr. Raybon’s general-causation opinions apply are listed at Exhibit A. To the extent the plaintiffs in those cases have not experienced or claimed to have infection, fistulae, or abscesses, Dr. Raybon’s infection-related testimony should be excluded.

VII. Dr. Raybon Is Not Qualified to Testify Regarding FDA Regulatory Requirements or Matters and His Proposed FDA Opinions Are Pure Speculation and Unreliable.

This Court has excluded FDA-related evidence in this and other mesh litigation. For that reason alone, Dr. Raybon’s FDA-related opinion testimony should be excluded. Dr. Raybon’s FDA-related opinion testimony should alternatively be excluded because Dr. Raybon is unqualified to render this opinion testimony. He admits he is not expert on FDA regulations or the FDA regulatory process for bringing medical devices to market, and that he has no training—formal or informal—on those subjects. Ex. E, Raybon 4/18/16 Dep. Tr. 217:2-21. Nevertheless, Dr. Raybon will offer the following opinions:

- Prolift was marketed “without first obtaining FDA 510(k) clearance”;
- Prolift devices were sold for three years “without [FDA] permission”;
- In 2011 FDA determined the safety and efficacy of Prolift devices “had not been established”; and
- Ethicon withdrew Prolift in response to FDA determining the devices were not safe and effective rather than conduct clinical trials FDA supposedly would have required.

Ex. C at 3.

This complete lack of experience or qualifications is readily apparent in the methodology Dr. Raybon used to develop those opinions. The basis for Dr. Raybon’s FDA opinions is that the information he used to develop them “was in the news.” Ex. E, Raybon 4/18/16 Dep. Tr. 190:9-16. The source of Dr. Raybon’s “news” is not properly peer-reviewed scientific literature or any other proper scientific publication; rather, Dr. Raybon’s source for his regulatory opinions is “one of the financials, either Wall Street Journal or Bloomberg.” Ex. E, Raybon 4/18/16 Dep. Tr.

190:17-24. Not surprisingly, Dr. Raybon concedes he does not even know if his regulatory opinions are accurate. *Id.* at 191:1-8 (“I will say that they did not get their—if they didn’t meet the requirements of the FDA, is that not illegal? I don’t know… I don’t know the legalese and all that. To me, they didn’t do the government requirements.”). In light of Dr. Raybon’s admissions that he is not an FDA expert and has no training whatsoever which would allow him to reliably develop any of these opinions, Dr. Raybon is not qualified to render any of these opinions (or any related opinions regarding any FDA-related regulatory issues).

Moreover, Dr. Raybon’s deposition testimony also shows he has no methodology—reliable or otherwise—for developing these opinions. Instead, he is merely reading an article from a financial journal and adopting select text from the article as his supposed “expert” opinion in an area where he has no qualifications. None of this even arguably passes *Daubert* muster in any sense. Dr. Raybon should be prohibited from testifying about any FDA matters.

VIII. Dr. Raybon’s Opinions Concerning Ethicon’s State of Mind, Knowledge, Motives, or Intentions, and His Narrative Review of Corporate Documents, Are Inadmissible.

The Court has repeatedly held that it will not permit expert testimony on “Ethicon’s knowledge, state of mind, or other matters related to corporate conduct and ethics,” because these matters “are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.” *In re Ethicon, Inc.*, 2014 WL 186872, at *6, *21; *see also, e.g., Wise*, 2015 WL 521202, at *4; *Huskey*, 29. F. Supp. 3d at 703. The Court has also excluded opinions that offer “simply a narrative review of corporate documents,” because such “opinions” are not helpful to the jury. *Huskey*, 29 F. Supp. 3d at 706; *see also Sanchez*, 2014 WL 4851989, at *32 (same); *Edwards*, 2014 WL 3361923, at *10 (same).

Despite these rulings, Dr. Raybon includes in his report page after page of proposed testimony on these topics. Ethicon respectfully requests that the Court enter rulings here,

consistent with its previous rulings, excluding any opinions of Dr. Raybon (1) regarding Ethicon's state of mind, knowledge, motives, intent, or other matters related to corporate conduct and ethics; or, (2) that are merely a narrative review of Ethicon's documents. This includes, but is not limited to, the following proposed testimony:

- “Ethicon personnel recognized the lack of safety and efficacy data available for the Prolift + M” (Ex. D at 4);
- Ethicon “recognized” pelvic organ prolapse is a functional disorder which is not life threatening before Prolift was marketed (Ex. C at 3);
- Ethicon knew about the “negative effects” of Gynemesh (*id.* at 21);
- Ethicon “acknowledged a lack of understanding” by implanting physicians of the concept of properly placing the Prolift devices so that they are tension free (*id.* at 26);
- Ethicon “recognized that only a few select physicians should perform the Prolift implantation procedures” (*id.* at 27);
- Ethicon internal documents reflect that consulting physicians “were concerned that the efficacy of the product had not been demonstrated by any data and that the risks associated with the product were serious” (*id.* at 3-4);
- “[T]he company’s medical personnel recognized that the amount of training necessary for these procedures was significant. The documents also show recognition that most physicians likely did not understand the proper technique for implanting Prolift” (*id.* at 23-24);
- Various statements indicating “Ethicon’s internal documents reflect” some knowledge which Dr. Raybon then indirectly imputes to Ethicon. For example, Dr. Raybon claims “Ethicon’s internal documents reflect that the polypropylene material used in the Gynemesh PS was *known* to cause ‘excessive’ and ‘chronic’ foreign body reaction and ‘intense’ and ‘chronic’ ‘inflammation’” (*id.* at 13) (emphasis added);²

² This is the same as saying Ethicon supposedly “knew” or “admitted” Gynemesh polypropylene causes chronic foreign body reaction and intense and chronic inflammation. This is an indirect attempt to engineer around the Court’s established restriction against this type of testimony. There are many examples of this in Dr. Raybon’s reports, and all should be excluded.

- Testimony that “if Ethicon knew or believed” something it was obligated to do something and acted inappropriately when it failed to so act (*see, e.g., id.* at 18-19) (“If Ethicon knew or believed that there may be risks specifically associated with the use of its Prolift product in a particular subset of patients, it was obligated to so advise surgeons. Basically, by not providing this information, Ethicon robbed each surgeon of the opportunity to provide true informed consent.”);³ and
- All statements offering a narrative review of Ethicon’s corporate documents. Ex. C at 3-4, 8, 10-11, 13, 14, 15, 16, 24, 25, 26, and 27.

CONCLUSION

For these reasons stated above, Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Brian Raybon, M.D.

Respectfully submitted,

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³ Jumping from an “if Ethicon knew” proposition to a conclusion that Ethicon acted inappropriately implicitly answers the “if” question and imputes the knowledge to Ethicon.

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CERTIFICATE OF SERVICE

I certify that on April 29, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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